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09/497,891	02/04/2000	Hermann Kuenzer	SCH-1692	8032
23599	7590	12/27/2005	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			QAZI, SABIHA NAIM	
		ART UNIT		PAPER NUMBER
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**MAILED**  
**DEC 27 2005**  
**GROUP 1600**

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/497,891

Filing Date: February 04, 2000

Appellant(s): KUENZER ET AL.

John A. Sopp \_\_\_\_\_  
Schering  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed on 1/31/2005.

**(1) Real Party in Interest**

A statement identifying the real party in interest is contained in the brief.

**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences that will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

Claims rejected:      Claims 53, 54 and 65.

Claims canceled:      Claims 1-52 and 66-89.

Claims withdrawn:      None.

Claims on appeal:      Claims 53, 54 and 65.

Claims objected:      Claim 55-64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**(4) *Status of Amendments After Final***

All the amendments have been entered.

**(5) *Summary of Invention***

The summary of invention contained in the brief is correct.

The remaining claims are 53, 54 and 65 are drawn to 3, 16-dihydroxyestra-1,3,5(10)-triene compound of formula I (as in claim 53) when R<sup>17</sup> is limited to hydrogen atom, fluoro

atom, a straight chain or branched chain saturated, optionally partially or completely fluorinated alkyl group with 1 to 10 carbon atoms in  $\alpha$  or  $\beta$ -position. The compounds excluded in original claims were estra-1, 3,5(10)-triene-3,16 $\alpha$ -diol and estra-1, 3,5(10)-triene-3,16 $\beta$ -diol. After the anticipation rejection over OJASOO et al. (Cancer Res. 38, 11 (1978), 4186-4196, AN 1979:66957 CAPLUS) and ROUSSEL-UCLAFAN (Patent FR. 5099, 19670626, AN 1970:3637 CAPLUS), Appellants have additionally disclaimed 16 $\beta$ -ethinylestra1, 3,5(10)-triene-3,16 $\alpha$ -diol and 16 $\alpha$ -ethinylestra1,3,5(10)-triene-3,16 $\beta$ -diol because these references disclose these compound.

**(6) *Issues***

The appellant's are silent on the statement of the issues in the brief.

The issue is as follows:

Whether or not two compounds disclaimed from the generic disclosure is new matter as defined by the negative limitation of claim 53. Claim 55-64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. These claims are amended from halogen to fluorine atom at R<sup>17</sup>. Claims 53-65 rejected under 35 U.S.C. 103(a) as being unpatentable over ARUNACHALAM et al. (Journal of Biological Chemistry, 254(13), 5900-5, 1979 (see page 5905; compounds 19a-c, the compounds of the following RNs: 71683-63-1, 71683-69-7, and 71683-70-0) is now withdrawn.

**(7) *Grouping of Claims***

Grouping of claims is correct.

**(8) *ClaimsAppealed***

Claims 53-65 contain(s) substantial errors as presented in the Appendix to the brief.

Since rejection under 35 U.S.C. 103(a) as being unpatentable over ARUNACHALAM et al. (Journal of Biological Chemistry, 254(13), 5900-5, 1979 is withdrawn therefore now claims 55-64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. (note, that the disclaimed species are not claimed in claims 55-64).

Accordingly, only claims 53, 54 and 65 stand rejected and are on appeal.

**(9) *Prior Art of Record***

The examiner in the rejection of the claims under appeal relies upon the following prior art.

1. OJASOO et al. (Cancer Res. 38, 11 (1978), 4186-4196)
2. ROUSSEL-UCLAFAN (Patent FR. 5099, 19670626, AN 1970:3637 CAPLUS)
3. ARUNACHALAM et al. (J. of Biol. Chem., 254(13), 5900-5, 1979).
4. In re Johnson (CCPA) 194 USPQ 187 (June 16, 1997); Ex parte Grasselli, et al. (Bd Pat App & Int) 231 USPQ 393 (June 30, 1983); Pudue Pharma L.P. Faulding Inc. US Court of Appeals Fed Cir. Nos. 99-1416-1433 (October 25, 2000)

**(10) *Grounds of Rejection***

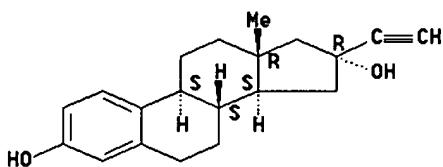
The following ground(s) of rejection are applicable to the appealed claims:

Claims 53, 54 and 65 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

If new matter in claim 53 is canceled, then the following 35 U.S.C. 102(b) rejection would be re-instated.

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Claims 53, 54 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by OJASOO et al. (Cancer Res. 38, 11 (1978), 4186-4196, AN 1979:66957 and AN 1970:3637 CAPLUS (ROUSSEL-UCLAF). The references disclose these compound, see compound nos. 85 and 86 on page 4194 of OJASOO's reference and RN 24989-47-7P CAPLUS.



#### Claim Rejections - 35 USC § 112

Claims 53, 54 and 65 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The proviso to disclaim the compounds 16 $\beta$ -ethinylestra1, 3,5(10)-triene-3,16 $\alpha$ -diol and 16 $\alpha$ -ethinylestra1,3,5(10)-triene-3,16 $\beta$ -diol is considered new matter because these compounds were not disclaimed in original claims or disclosure; and there is no positive recitation of these compounds in the specification or the original claims. They are disclosed only in that they are part of a generic disclosure.

#### **(11) Response to Appellants' Arguments**

- Examiner respectfully disagree with the argument that "claims 53, 54 and 65, on

appeal, have an adequate written description in the original disclosure and thus, are proper under 35 U.S.C. 112, first paragraph”.

- The rejection is based on the proviso in claim 53, which is not supported by an adequate written description in the original disclosure. The compounds disclaimed are  $16\beta$ -ethinylestral, 3,5(10)-triene-3,16 $\alpha$ -diol and 16 $\alpha$ -ethinylestra1,3,5(10)-triene-3,16 $\beta$ -diol.
- MPEP 2173.05(i) states: “Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977). In *In re Johnson*, the court noted that any negative limitation or exclusionary proviso *must have basis in the original disclosure*. Only if alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. In the present case the negative limitation/exclusionary proviso does not have basis in the original disclosure, and the alternative elements were not positively recited in the specification, they are generically disclosed, so the Appellants’ argument is not relevant to the current issues.
- In the present case compounds were generically disclosed and claimed (claim 53). After the anticipation rejection Appellants have disclaimed the two specific compounds, which were anticipated.
- See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), aff’d mem., 738 F.2d 453 (Fed. Cir. 1984). Any claim containing a negative limitation, which does not

have basis in the original disclosure, should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement.

- The instant claims 53, 54 and 65 therefore are rejected under 35 U.S.C. 112, first paragraph, under instruction from MPEP 2173.05(i), because they contain a negative limitation that does not have basis in the original disclosure.
- In *Purdue Pharma LP v Faulding, Inc.*, 230 F.3d 1320, 1326, 56 USPQ2d 1481, 1486 (Fed. Cir. 2000), the court noted that with respect to *In re Ruschig*, 371 F.2d 990, 154 USPQ 118 (CCPA 1967),

“Ruschig makes clear that one cannot disclose a forest in the original application, and then later pick out a tree of the forest and say, “here is my invention”. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure.”

- *Purdue* is relevant in this case, because the Appellants disclosed a genus (“a forest”) in the original application, then later picked out two specific compounds (“a tree of the forest”), and are now saying, “here is my invention”. In order to satisfy the written description requirement, according to *Purdue*, the Appellants must disclose the specific compounds in the originally filed disclosure.” (See (56 USPQ2D 1481)).
- More from *Purdue*: The case of *In re Ruschig*, 379 F.2d 990, 154 USPQ 118 (CCPA 1967), is instructive here (see page 1487). The claim at issue in that case was directed to a single compound. The appellants argued that, although the compound itself was not disclosed, one skilled in the art would find support for

the claimed compound in the general disclosure of the genus of compounds to which the claimed compound belonged. The Ruschig court rejected that argument, stating: [i]t is an old custom in the woods to mark trails by making blaze marks on the trees. It is of no help in finding a trail or in finding one's way through the woods where the trails have disappeared-or have not yet been made, which is more like the case here-to be confronted simply by a large number of unmarked trees. We are looking for blaze marks, which single out particular trees. We see none. *Id.* at 994-95, 154 USPQ at 122.

- Arguments regarding claims 55-64 are moot because claims are amended and the rejection over ARUNACHALAM et al. (*Journal of Biological Chemistry*, 254(13), 5900-5, 1979) is withdrawn.
- Examiner believes that since the two compounds 16 $\beta$ -ethinylestra1, 3,5(10)-triene-3,16 $\alpha$ -diol and 16 $\alpha$ -ethinylestra1,3,5(10)-triene-3,16 $\beta$ -diol were not specifically disclosed in the specification or in original claims and were generically taught, disclaimer in claim 53 containing a negative limitation to exclude these compounds, does not have basis in the original disclosure, and should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

November 15, 2005

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